IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8881

Bartle, J. May 30, 2012

Sandra S. Steeves ("Ms. Steeves" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust").[2] Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[3]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Edward P. Wattawa, claimant's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In October, 2004, claimant submitted an amended Green Form[4] to the Trust signed by her attesting physician, Janice D. Christensen, M.D. Based on an echocardiogram dated February 4, 2003, Dr. Christensen attested in Part II of claimant's amended Green Form that Ms. Steeves suffered from

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3. (...continued)
presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

4. The Show Cause Record also contains several Green Forms that claimant submitted prior to the October, 2004 Green Form. These Green Forms, however, are not at issue in this claim.

severe aortic regurgitation. Dr. Christensen also attested that claimant had surgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™.[5] Based on such findings, claimant would be entitled to Matrix A-1, Level III benefits in the amount of $675,380.[6]

Under the Settlement Agreement, the presence of aortic sclerosis in Diet Drug Recipients who were sixty (60) years of age or older at the time they were first diagnosed as FDA Positive[7] requires the payment of reduced Matrix Benefits. See Settlement Agreement § IV.B.2.d.(2)(c)i)c). Ms. Steeves was first diagnosed as FDA Positive by echocardiogram on July 17, 2002, when she was sixty (60) years of age. In the report of this echocardiogram, the reviewing cardiologist, Michael L. Hinnen, M.D., noted that there was "[s]light thickening of the cusps" and that "[t]he aortic leaflets are

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5. In addition, Dr. Christensen attested that claimant suffered from an abnormal left atrial dimension, an abnormal left ventricular end-systolic dimension, a reduced ejection fraction in the range of 40% to 49%, and New York Heart Association Functional Class I symptoms. These conditions, however, are not relevant to this claim.

6. Under the Settlement Agreement, a claimant is entitled to Level III benefits if he or she suffers from "left sided valvular heart disease requiring ... [s]urgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™." Settlement Agreement § IV.B.2.c.(3)(a).

7. FDA Positive is defined, in pertinent part, as "mild or greater regurgitation of the aortic valve...." Settlement Agreement § I.22.a.

thickened." Dr. Christensen, however, attested in claimant's amended Green Form that Ms. Steeves did not suffer from aortic sclerosis. As the Trust does not contest claimant's entitlement to Level III benefits, the only issue before us is whether claimant is entitled to payment on Matrix A-1 of Matrix B-1.

In May, 2005, the Trust forwarded the claim for review by Waleed N. Irani, M.D., one of its auditing cardiologists.[8] In audit, Dr. Irani concluded that there was no reasonable medical basis for Dr. Christensen's finding that Ms. Steeves did not have aortic sclerosis, noting that "[claimant] clearly has aortic sclerosis on [echocardiogram] which was commented on by original reading physician [and] noted on official [echocardiogram] report."

Based on the auditing cardiologist's finding that claimant had aortic sclerosis, the Trust issued a post-audit determination that Ms. Steeves was entitled only to Matrix B-1, Level III benefits. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[9] In contest, claimant argued that

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8. Pursuant to Pretrial Order ("PTO") No. 3882 (Aug. 26, 2004), all Level III, Level IV, and Level V Matrix claims were subject to the Parallel Processing Procedures ("PPP"). As Wyeth did not agree that claimant had a Matrix A-1, Level III claim, pursuant to the PPP, the Trust audited the claim.

9. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition (continued...)

her echocardiogram of February 4, 2003 and the report from her April 10, 2003 surgery show that she did not have aortic sclerosis. In support of this argument, Ms. Steeves submitted a letter from Neil K. Worrall, M.D., the surgeon who performed claimant's aortic valve replacement. Dr. Worrall stated that the "findings at surgery were that of ... very thinned out valve leaflets without any evidence of aortic valve scarring or sclerosis." Dr. Worrall further noted that claimant's pathology report:

> [D]emonstrated three fragments of valve tissue that are consistent with myxoid degeneration but no distinct calcification or scarring or thickening noted. In addition, [claimant's] preoperative echocardiogram on February 4, 2003 ... was found to have a trileaflet aortic valve with normal motion with moderate to severe regurgitation without evidence of leaflet thickening or sclerosis.

The Trust then issued a final post-audit determination again determining that Ms. Steeves was entitled only to Matrix B-1, Level III benefits. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c).

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9. (...continued)
of Matrix Compensation Claims in Audit, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to the claim of Ms. Steeves.

The Trust then applied to the court for issuance of an Order to show cause why this claim should be paid. On February 13, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 5986 (Feb. 13, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on December 6, 2006, and claimant submitted a surreply on January 29, 2007. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[10] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical

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10. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In cases, such as here, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she did not have aortic sclerosis. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's amended Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Steeves asserts that her February 4, 2003 echocardiogram report and the report from her aortic valve replacement indicate that she did not have aortic sclerosis. Claimant also relies on letters from Dr. Worrall and Alexandra Wardzala, M.D., the physician who prepared the pathology report on the aortic valve leaflets from claimant's surgery. Dr. Worrall again stated that claimant did not have aortic sclerosis, and that his "operative note specifically details that [claimant's] leaflets were very thinned out, which is the exact opposite of aortic valve sclerosis." Dr. Wardzala

also indicated that claimant's aortic valve specimen showed no evidence of aortic sclerosis, stating that "[t]he diagnosis of myxoid degeneration was rendered in April of 2003, and it is specifically the opposite of aortic valve sclerosis. The [claimant's] aortic valve was pliable and did not require decalcification, which is usually required had there been aortic sclerosis."

The Trust contends that the operative report "is at best ambiguous with respect to whether or not [claimant] had aortic sclerosis." In addition, the Trust points out that both the report of claimant's July 17, 2002 echocardiogram and the pre-operative report prepared in connection with claimant's aortic valve replacement surgery indicate thickened aortic leaflets, which is consistent with the presence of aortic sclerosis.

In her surreply, claimant states that Dr. Irani failed to note that her surgeon, Dr. Worrall, completed a Green Form[11] shortly after her aortic valve replacement in which he attested that claimant did not have aortic sclerosis at the time she was first diagnosed with mild or greater aortic regurgitation.

The Technical Advisor, Dr. Vigilante reviewed claimant's echocardiograms and concluded that there was no

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11. This Green Form was submitted to the Trust in April, 2003, and was based on an echocardiogram dated April 2, 2003.

reasonable medical basis for the attesting physician's finding that Ms. Steeves did not have aortic sclerosis. Specifically, Dr. Vigilante stated, in relevant part, that:

> I reviewed the Claimant's echocardiogram of July 17, 2002.... The aortic valve was a tri-leaflet structure. All three leaflets were mildly thickened. This was noted in the parasternal long axis, parasternal short axis, and apical long axis views. There was no highly refractile material consistent with calcification. However, in all views, there was increased echo density and, therefore, increased thickness of leaflets.... This mild thickening of the leaflets is consistent with mild aortic sclerosis or scarring of the leaflets in the absence of calcification.... The finding of mild thickening or sclerosis of the aortic leaflets is consistent with the echocardiogram report of July 17, 2002 dictated by Dr. Michael Hinnen. The finding is also consistent with the surgical pathology report which demonstrated areas of slight yellow thickening of the aortic valve fragments.

Dr. Vigilante reached a similar determination upon review of the February 4, 2003 echocardiogram, noting that:

> Once again, mild thickening of a trileaflet aortic valve was noted in the parasternal long axis, parasternal short axis, and apical long axis views. There were increased echo densities of the aortic valve but no calcification or significantly increased reflectance was noted.

Claimant maintains that the auditing cardiologist and Technical Advisor failed to find any references of aortic sclerosis in her medical records, that sclerosis advances to stenosis and no stenosis was found, and that the mention of

"slight thickening" in the records was rebutted by the operative report and subsequent letters from Dr. Worrall and Dr. Wardzala. Claimant asserts that, except for her treating physician's diagnosis that she suffers from myxoid degeneration, which she claims the Technical Advisor erroneously associated with aortic sclerosis, all of the other findings by the Technical Advisor can be attributed to fen-phen.

After reviewing the entire Show Cause record, we find claimant's arguments are without merit. First, claimant does not refute the specific determinations of the Technical Advisor. This claim for Matrix Benefits is predicated upon the July 17, 2002 and February 4, 2003 echocardiograms cited in claimant's Green Forms. Dr. Irani, the auditing cardiologist, and Dr. Vigilante determined that these echocardiograms demonstrated aortic sclerosis. Dr. Vigilante based his opinion, in part, upon an observation that claimant's aortic leaflets were mildly thickened. Dr. Hinnen noted on claimant's July 17, 2002 echocardiogram report that "[t]he aortic leaflets are thickened...." Dr. Wardzala noted on claimant's April 10, 2003 surgical pathology report that there were "[a]reas of slight yellow thickening...." Dr. Worrall's declaration fails to address these findings. On this basis alone, claimant has failed

to meet her burden of demonstrating that there is a reasonable medical basis for her claim.[12]

In addition, the court rejects Dr. Worrall's assertion that claimant is entitled to Matrix A benefits because her aortic valve degeneration is "consistent with fen-phen use." Causation is not at issue in resolving this claim for Matrix Benefits. Rather, Ms. Steeves is required to show that she meets the objective criteria set forth in the Settlement Agreement. As we previously concluded:

> Class members do not have to demonstrate that their injuries were caused by ingestion of Pondimin and Redux in order to recover Matrix Compensation Benefits. Rather, the Matrices represent an objective system of compensation whereby claimants need only provide that they meet objective criteria to determine which matrix is applicable, which matrix level they qualify for and the age at which that qualification occurred....

PTO No. 1415 at 51 (Aug. 28, 2000). In addition, we noted:

> ... [I]ndividual issues relating to causation, injury and damages also disappear because the settlement's objective criteria provide for an objective scheme of compensation.

Id. at 97. If claimants are not required to demonstrate causation, the converse also is true, namely, in applying the

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12. Although claimant states her myxoid degeneration is "the opposite of aortic valve sclerosis," her response to the Technical Advisor Report fails to identify any diagnosis to rebut the multiple observations that her aortic valve leaflets were thickened, which is consistent with aortic valve sclerosis.

terms of the Settlement Agreement, the Trust does not need to establish that a reduction factor caused the degeneration at issue. The Settlement Agreement unequivocally requires a claim to be reduced to Matrix B-1 if the claimant suffered from aortic sclerosis and was sixty (60) years of age or older at the time he or she was first diagnosed as FDA Positive. See Settlement Agreement § IV.B.2.d.(2)(c)i)(c). We must apply the Settlement Agreement as written. Accordingly, claimant's argument that she did not have a heart condition prior to the Diet Drug use, even if true, is irrelevant.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she did not have aortic sclerosis at the time she was first diagnosed as FDA Positive. Therefore, we will affirm the Trust's denial of the claim of Ms. Steeves for Matrix A-1 benefits and the related derivative claim submitted by her spouse.